K131515

510(k) SUMMARY

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	AUG 14 2013
Date Summary Prepared:	August 5, 2013	
Device:	Trade Name:	ACE γ-GT Reagent
	Classification:	Class 1
	Common/Classification Name:	Colorimetric Method, Gamma-Glutamyl Transpeptidase (21 C. F.R. § 862.1360) Product Code JPZ
	Trade Name:	ACE Lipase Reagent
	Classification:	Class 1
	Common/Classification Name:	Lipase-Esterase, Enzymatic, Photometric, Lipase (21 C. F.R. § 862.1465) Product Code CHI
	Trade Name:	ACE T4 Reagent
	Classification:	Class 2
	Common/Classification Name:	Enzyme Immunoassay, Non-Radiolabeled, Total Thyroxine (21 C. F.R. § 862.1700) Product Code KLI
Predicate Devices:	Manufacturer for reagent system predicates: Alfa Wassermann ACE Clinical Chemistry System and ACE Reagents (K930104, K981377, K113253, K113382, K113438, K113437)	
Device Descriptions:	In the ACE γ-GT Reagent assay, γ-GT in serum or heparin plasma catalyzes the transfer of the γ-glutamyl group from L-γ-glutamyl-3-carboxy-4-nitroanilide to glycylglycine in the reagent. The product, 5-amino-2-nitrobenzoate, absorbs strongly at 408 nm. The rate of increase in absorbance, monitored bichromatically at 408 nm/486 nm, is directly proportional to the γ-GT activity in the sample.	

	In the ACE Lipase Reagent Assay, lipase in serum or heparin plasma acts on a natural substrate, 1,2-diglyceride, to liberate 2-monoglyceride. This is hydrolyzed by monoglyceride lipase (a highly specific enzyme for monoglyceride) into glycerol and free fatty acid. Glycerol kinase acts on glycerol to form glycerol-3-phosphate, which is in turn acted on by glycerol-3-phosphate oxidase to generate hydrogen peroxide. Peroxidase converts the hydrogen peroxide, 4-Aminoantipyrine and TOOS (N-ethyl-N-(2-hydroxy-3-sulfopropyl)-m-toluidine) into a quinine dye. The rate of formation of the dye, determined bichromatically at an absorbance of 573 nm/692 nm, is proportional to the lipase activity in the sample. The ACE T4 Assay is a homogeneous enzyme immunoassay using ready-to-use liquid ACE T4 Reagent. The assay uses 8-anilino-1-naphthalene sulfonic acid (ANS) to dissociate thyroxine from the plasma binding proteins. Using specific antibodies to thyroxine, this assay is based on the competition of glucose-6-phosphate dehydrogenase (G6PD) labeled thyroxine and the dissociated thyroxine in the sample for a fixed amount of specific antibody binding sites. In the absence of thyroxine from the sample, the thyroxine labeled G6PD in the second reagent is bound by the specific antibody in the first reagent, inhibiting the enzyme's activity. The enzyme G6PD catalyzes the oxidation of glucose-6-phosphate (G6P) with nicotinamide adenine dinucleotide (NAD^+) to form 6-phosphogluconate and reduced nicotinamide adenine dinucleotide (NADH). NADH strongly absorbs at 340 nm whereas NAD^+ does not. The rate of conversion, determined by measuring the increase in absorbance bichromatically at 340 nm/505 nm during a fixed time interval, is directly proportional to the amount of thyroxine in the sample. The concentration of thyroxine is determined automatically by the ACE Clinical Chemistry Systems using a logarithmic calibration curve established with calibrators, which are provided separately.

Intended Use:	Indications for Use: The ACE γ-GT Reagent is intended for the quantitative determination of gamma-glutamyltransferase activity **in serum and lithium heparin plasma** using the ACE, ACE *Alera*, and ACE Axcel Clinical Chemistry Systems. Gamma-glutamyltransferase measurements are used in the diagnosis and treatment of liver diseases such as alcoholic cirrhosis and primary and secondary liver tumors. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only. The ACE Lipase Reagent is intended for the quantitative determination of lipase activity **in serum and lithium heparin plasma** using the ACE, ACE *Alera*, and ACE Axcel Clinical Chemistry Systems. Lipase measurements are used in diagnosis and treatment of diseases of the pancreas such as acute pancreatitis and obstruction of the pancreatic duct. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only. The ACE T4 Reagent is intended for the quantitative determination of total thyroxine (T4) **in serum and lithium heparin plasma** using the ACE, ACE *Alera*, and ACE Axcel Clinical Chemistry Systems. Total thyroxine measurements are used in the diagnosis and treatment of thyroid diseases. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only.
Technological Characteristics:	The ACE γ-GT Reagent consists of two reagent bottles (γ-GT Buffer and γ-GT Substrate). The reagent contains L-γ-glutamyl-3-carboxy-4-nitroanilide, glycylglycine and buffer. The ACE Lipase Reagent is composed of two reagent bottles (Lipase Reagent and Lipase Activator). The Lipase Reagent (R1) contains: 1,2-diglyceride, monoglyceride lipase, glycerol kinase, glycerol-3-phosphate oxidase, N-ethyl-N-(2-hydroxy-3-sulfopropyl)-m-toluidine, ATP, peroxidase, colipase, human serum albumin, ascorbate oxidase, cholic acid and buffer. The Lipase Activator contains: deoxycholate, 4-aminoantipyrene and buffer. The ACE T4 Reagent is composed of two reagent bottles (Antibody/Substrate Reagent and Enzyme Conjugate Reagent). The Antibody/Substrate Reagent (R1) contains: mouse monoclonal anti-thyroxine antibody, 8-anilino-1-naphthalene sulfonic acid, glucose-6-phosphate, nicotinamide adenine dinucleotide and Tris buffer. The Enzyme Conjugate Reagent (R2) contains: glucose-6-phosphate dehydrogenase labeled with thyroxine and Tris buffer.

Device Comparison with Predicate

Comparison of similarities and differences with predicate device

ACE γ-GT Reagent

γ-GT	Candidate Device	Predicate Device k930104 (ACE γ-GT Reagent)
Intended Use/Indications for Use	The ACE γ-GT Reagent is intended for the quantitative determination of gamma-glutamyltransferase activity.	Same
Platforms	ACE, ACE *Alera*® and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	Not a calibrated test	Same
On Board Stability	30 days	Same
Sample Type	Serum and lithium heparin plasma	**Serum**
Sample Volume	5 µL	Same
Reaction Volume	170 µL	Same
Expected values	Male: 13-68 U/L Female: 11-48 U/L	Same
Measuring range	7-950 U/L	Same
Sample Stability	Separated from cells, gamma-glutamyltransferase is stable 7 days at 4-8°C and up to 1 year at -20°C.	Same

ACE Lipase Reagent

Lipase	Candidate Device	Predicate Device k930104 (ACE Lipase Reagent)
Intended Use/Indications for Use	The ACE Lipase Reagent is intended for the quantitative determination of lipase activity.	Same
Platforms	ACE, ACE *Alera*® and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	20 days	Same
On Board Stability	20 days	Same
Sample Type	Serum and lithium heparin plasma	**Serum**
Sample Volume	3 µL	Same
Reaction Volume	263 µL	Same
Expected values	<60 U/L	Same
Measuring range	15-700 U/L	Same
Sample Stability	Stable for 7 days at 20-25°C, three weeks at 4-8°C and at -20°C for one year.	Same

ACE T4 Reagent

T4	Candidate Device	Predicate Device k981377 (ACE T4 Reagent)
Intended Use/Indications for Use	ACE T4 Reagent is intended for the quantitative determination of total thyroxine (T4).	Same
Platforms	ACE, ACE *Alera*® and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	5 days	Same
On Board Stability	30 days	Same
Sample Type	Serum and lithium heparin plasma	**Serum**
Sample Volume	5 µL	Same
Reaction Volume	315 µL	Same
Expected values	5.0 - 12.0 µg/dL	Same
Measuring range	1.3-19.6 µg/dL	Same
Sample Stability	Specimen stable for 7 days at 4-8°C and 1 month at -20°C.	Same

Performance Data:

In-House Precision – Serum vs. Plasma

Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE, ACE *Alera* and ACE Axcel Clinical Chemistry Systems

In-House Precision: Serum vs. Plasma – ACE γ-GT Reagent

	Precision (SD, %CV)								
γ-GT U/L	ACE			ACE *Alera*			ACE Axcel		
	Mean	Within-Run	Total	Mean	Within-Run	Total	Mean	Within-Run	Total
Serum Low	38	0.9, 2.4%	1.2, 3.1%	39	0.9, 2.4%	1.0, 2.5%	37	0.7, 1.8%	0.9, 2.3%
Plasma Low	38	0.4, 1.0%	0.8, 2.2%	40	0.7, 1.9%	0.7, 1.9%	38	0.7, 2.0%	0.9, 2.4%
Serum Mid	313	2.4, 0.8%	2.8, 0.9%	314	3.9, 1.3%	4.5, 1.4%	318	2.0, 0.6%	2.6, 0.8%
Plasma Mid	316	2.4, 0.8%	3.0, 0.9%	317	1.7, 0.5%	2.4, 0.8%	319	2.6, 0.8%	2.9, 0.9%
Serum High	602	2.3, 0.4%	2.6, 0.4%	601	4.2, 0.7%	6.1, 1.0%	606	4.2, 0.7%	5.4, 0.9%
Plasma High	605	3.6, 0.6%	4.4, 0.7%	604	4.3, 0.7%	4.9, 0.8%	608	4.4, 0.7%	5.9, 1.0%

In-House Precision: Serum vs. Plasma – ACE Lipase Reagent

	Precision (SD, %CV)								
Lipase U/L	ACE			ACE *Alera*			ACE Axcel		
	Mean	Within-Run	Total	Mean	Within-Run	Total	Mean	Within-Run	Total
Serum Low	47	1.7, 3.6%	3.2, 6.7%	45	1.6, 3.5%	2.9, 6.4%	44	2.8, 6.3%	3.0, 6.9%
Plasma Low	48	2.2, 4.6%	3.2, 6.6%	47	1.5, 3.2%	3.5, 7.4%	48	2.6, 5.5%	3.1, 6.4%
Serum Mid	283	5.1, 1.8%	13.1, 4.6%	286	3.8, 1.3%	19.1, 6.7%	280	3.3, 1.2%	4.0, 1.4%
Plasma Mid	278	2.6, 0.9%	11.5, 4.1%	278	2.2, 0.8%	20.0, 7.2%	272	4.8, 1.8%	6.8, 2.5%
Serum High	545	3.9, 0.7%	24.3, 4.5%	547	4.3, 0.8%	37.5, 6.9%	534	5.5, 1.0%	9.5, 1.8%
Plasma High	524	5.9, 1.1%	18.9, 3.6%	528	5.0, 1.0%	31.7, 6.0%	518	5.8, 1.1%	10.2, 2.0%

In-House Precision: Serum vs. Plasma – ACE T4 Reagent

	Precision (SD, %CV)								
T4 µg/dL	ACE			ACE *Alera*			ACE Axcel		
	Mean	Within-Run	Total	Mean	Within-Run	Total	Mean	Within-Run	Total
Serum Low	7.7	0.17, 2.2%	0.35, 4.5%	7.7	0.15, 2.0%	0.19, 2.4%	7.9	0.18, 2.3%	0.21, 2.6%
Plasma Low	7.8	0.28, 3.5%	0.29, 3.8%	7.8	0.14, 1.9%	0.21, 2.7%	8.0	0.15, 1.9%	0.21, 2.7%
Serum Mid	12.7	0.46, 3.6%	0.63, 4.9%	12.5	0.24, 1.9%	0.48, 3.9%	12.9	0.30, 2.3%	0.43, 3.4%
Plasma Mid	13.1	0.24, 1.8%	0.50, 3.8%	12.9	0.28, 2.2%	0.67, 5.2%	13.2	0.19, 1.5%	0.71, 5.4%
Serum High	17.3	0.50, 2.9%	0.74, 4.3%	17.1	0.27, 1.6%	0.57, 3.3%	17.5	0.50, 2.9%	0.75, 4.3%
Plasma High	17.6	0.76, 4.3%	0.76, 4.3%	17.4	0.41, 2.4%	0.44, 2.6%	17.6	0.60, 3.4%	0.60, 3.4%

Performance Data:

In-House Matrix Comparison – Serum vs. Plasma

Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE, ACE *Alera* and ACE Axcel Clinical Chemistry Systems

In-House Matrix Comparison: Serum vs. Plasma – ACE γ-GT Reagent

System	Range	Results - Serum vs. Plasma
ACE 100 pairs	9 - 886 U/L	Slope: 0.972 Intercept: 1.5 Correlation: 0.9990 Std. Error Est: 7.9 Confidence Interval Slope: 0.964 to 0.981 Confidence Interval Intercept: -0.3 to 3.3
ACE *Alera* 97 pairs	9 - 841 U/L	Slope: 0.960 Intercept: 2.8 Correlation: 0.9989 Std. Error Est: 8.2 Confidence Interval Slope: 0.951 to 0.969 Confidence Interval Intercept: 0.8 to 4.7
ACE Axcel 53 pairs	10 - 910 U/L	Slope: 0.987 Intercept: 4.0 Correlation: 0.9973 Std. Error Est: 16.5 Confidence Interval Slope: 0.967 to 1.008 Confidence Interval Intercept: -1.8 to 9.8

In-House Matrix Comparison: Serum vs. Plasma – ACE Lipase Reagent

System	Range	Results - Serum vs. Plasma
ACE 42 pairs	16 - 642 U/L	Slope: 1.024 Intercept: -2.5 Correlation: 0.9992 Std. Error Est: 6.4 Confidence Interval Slope: 1.011 to 1.038 Confidence Interval Intercept: -5.0 to -0.1
ACE *Alera* 43 pairs	19 - 640 U/L	Slope: 1.022 Intercept: -0.9 Correlation: 0.9994 Std. Error Est: 5.5 Confidence Interval Slope: 1.010 to 1.033 Confidence Interval Intercept: -3.0 to 1.2
ACE Axcel 62 pairs	15 - 627 U/L	Slope: 0.980 Intercept: -2.0 Correlation: 0.9947 Std. Error Est: 13.2 Confidence Interval Slope: 0.954 to 1.007 Confidence Interval Intercept: -5.9 to 2.0

In-House Matrix Comparison: Serum vs. Plasma – ACE T4 Reagent

System	Range	Results - Serum vs. Plasma
ACE 55 pairs	2.0 - 19.3 µg/dL	Slope: 0.963 Intercept: 0.35 Correlation: 0.9847 Std. Error Est: 0.54 Confidence Interval Slope: 0.916 to 1.009 Confidence Interval Intercept: -0.03 to 0.73
ACE *Alera* 55 pairs	1.9 - 18.6 µg/dL	Slope: 0.976 Intercept: 0.17 Correlation: 0.9870 Std. Error Est: 0.49 Confidence Interval Slope: 0.933 to 1.019 Confidence Interval Intercept: -0.18 to 0.51
ACE Axcel 55 pairs	2.1 - 17.6 µg/dL	Slope: 1.007 Intercept: 0.01 Correlation: 0.9841 Std. Error Est: 0.55 Confidence Interval Slope: 0.958 to 1.057 Confidence Interval Intercept: -0.38 to 0.40

Performance Data:

Precision - POL

POL – Precision for ACE and ACE *Alera* Clinical Chemistry Systems

(Note: Refer to previously cleared submissions k113382, k113438 and k113437 for ACE Axcel POL data)

γ-GT		ACE Result			ACE *Alera* Result		
			U/L SD, %CV			U/L SD, %CV	
Lab	Sample	Mean	Within-Run	Total	Mean	Within-Run	Total
In-House	1	19	0.9	1.7	19	1.4	1.5
			4.6%	9.2%		7.1%	7.9%
POL 1	1	17	1.1	1.7	18	0.7	0.9
			6.4%	9.8%		4.2%	5.2%
POL 2	1	15	0.6	1.0	18	0.9	1.0
			4.0%	6.8%		4.8%	5.6%
POL 3	1	16	0.8	1.0	18	0.9	1.0
			4.9%	6.2%		5.2%	5.3%
In-House	2	297	2.0	2.0	298	3.3	3.7
			0.7%	0.7%		1.1%	1.2%
POL 1	2	286	3.0	3.3	287	2.2	2.6
			1.0%	1.1%		0.8%	0.9%
POL 2	2	284	2.5	2.9	315	1.9	2.3
			0.9%	1.0%		0.6%	0.7%
POL 3	2	287	2.2	4.1	299	2.7	2.8
			0.8%	1.4%		0.9%	1.0%
In-House	3	523	5.2	5.9	524	2.6	3.3
			1.0%	1.1%		0.5%	0.6%
POL 1	3	502	3.1	4.0	503	4.5	4.5
			0.6%	0.8%		0.9%	0.9%
POL 2	3	500	5.5	5.6	561	3.5	3.5
			1.1%	1.1%		0.6%	0.6%
POL 3	3	496	4.6	6.3	528	3.0	4.6
			0.9%	1.3%		0.6%	0.9%

Performance Data:

Precision - POL

POL – Precision for ACE and ACE *Alera* Clinical Chemistry Systems

Lipase		ACE Result			ACE *Alera* Result		
			U/L SD, %CV			U/L SD, %CV	
Lab	Sample	Mean	Within-Run	Total	Mean	Within-Run	Total
In-House	1	23	1.9	2.5	24	2.0	2.0
			8.2%	10.9%		8.7%	8.7%
POL 1	1	24	2.3	3.1	23	2.2	2.7
			9.4%	12.8%		9.6%	12.0%
POL 2	1	21	0.9	1.4	21	1.8	1.9
			4.5%	6.8%		8.5%	8.9%
POL 3	1	24	1.5	2.0	22	1.1	2.3
			6.3%	8.0%		5.0%	10.5%
In-House	2	161	2.8	4.2	158	2.4	3.0
			1.7%	2.6%		1.5%	1.9%
POL 1	2	167	2.5	6.8	154	3.8	7.7
			1.5%	4.0%		2.5%	5.0%
POL 2	2	134	1.7	5.4	154	3.8	3.9
			1.3%	4.1%		2.5%	2.5%
POL 3	2	152	3.3	5.5	148	1.9	5.2
			2.2%	3.6%		1.3%	3.5%
In-House	3	321	4.3	7.6	315	2.8	11.5
			1.3%	2.4%		0.9%	3.7%
POL 1	3	327	7.7	12.3	292	9.9	14.5
			2.3%	3.8%		3.4%	5.0%
POL 2	3	265	4.9	13.3	310	2.5	6.3
			1.8%	5.0%		0.8%	2.0%
POL 3	3	289	3.3	8.7	293	4.2	12.3
			1.2%	3.0%		1.4%	4.2%

Performance Data:

Precision - POL

POL – Precision for ACE and ACE *Alera* Clinical Chemistry Systems

T4		ACE Result			ACE *Alera* Result		
			µg/dL SD, %CV			µg/dL SD, %CV	
Lab	Sample	Mean	Within-Run	Total	Mean	Within-Run	Total
In-House	1	4.2	0.10	0.17	4.1	0.09	0.17
			2.5%	4.1%		2.2%	4.3%
POL 1	1	4.0	0.09	0.11	4.3	0.09	0.15
			2.3%	2.7%		2.2%	3.5%
POL 2	1	4.2	0.12	0.14	4.1	0.12	0.18
			2.8%	3.3%		2.8%	4.3%
POL 3	1	4.2	0.11	0.11	3.9	0.17	0.20
			2.7%	2.7%		4.4%	5.0%
In-House	2	10.2	0.15	0.19	10.1	0.14	0.33
			1.5%	1.9%		1.4%	3.2%
POL 1	2	9.9	0.19	0.27	10.3	0.41	0.43
			1.9%	2.7%		4.0%	4.2%
POL 2	2	10.6	0.40	0.52	10.1	0.25	0.29
			3.8%	4.9%		2.5%	2.9%
POL 3	2	10.5	0.14	0.20	10.1	0.31	0.49
			1.3%	1.9%		3.1%	4.9%
In-House	3	16.3	0.35	0.83	16.0	0.27	0.41
			2.2%	5.1%		1.7%	2.6%
POL 1	3	16.1	0.27	0.41	16.4	0.58	0.89
			1.7%	2.5%		3.5%	5.4%
POL 2	3	17.1	0.28	0.81	16.3	0.46	0.76
			1.7%	4.7%		2.8%	4.7%
POL 3	3	17.3	0.28	0.33	17.6	0.79	0.97
			1.6%	1.9%		4.5%	5.5%

Performance Data:

Method Comparison - POL on ACE

POL – Method Comparison for ACE Clinical Chemistry System

Reagent	Statistic	In-House (x) vs. ACE POL 1 (y)	In-House (x) vs. ACE POL 2 (y)	In-House (x) vs. ACE POL 3 (y)
γ-GT	n	51	51	51
	Range	15 to 866	15 to 866	15 to 866
	Regression	y = 0.964x + 0.7	y = 0.976x – 2.7	y = 0.971x – 0.8
	Correlation	0.9997	0.9998	0.9999
	Std. Error Est.	4.2	4.2	2.6
	CI Slope	0.958 to 0.971	0.970 to 0.982	0.967 to 0.975
	CI Intercept	-0.7 to 2.0	-4.0 to -1.3	-1.6 to 0.1
Lipase	n	54	51	51
	Range	15 to 644	15 to 676	15 to 676
	Regression	y = 1.002x + 0.0	y = 0.994x – 5.3	y = 1.031x – 2.3
	Correlation	0.9986	0.9966	0.9987
	Std. Error Est.	9.6	11.6	7.5
	CI Slope	0.988 to 1.017	0.970 to 1.017	1.016 to 1.047
	CI Intercept	-3.1 to 3.1	-9.1 to -1.5	-4.8 to 0.2
T4	n	50	50	50
	Range	1.5 to 18.6	1.5 to 18.6	1.5 to 18.6
	Regression	y = 1.010x - 0.04	y = 1.019x - 0.07	y = 1.017x - 0.09
	Correlation	0.9936	0.9908	0.9921
	Std. Error Est.	0.27	0.33	0.31
	CI Slope	0.977 to 1.043	0.979 to 1.059	0.980 to 1.054
	CI Intercept	-0.29 to 0.22	-0.38 to 0.24	-0.38 to 0.19

Performance Data:

Method Comparison - POL on ACE *Alera*

POL – Method Comparison for ACE *Alera* Clinical Chemistry System

Reagent	Statistic	In-House (x) vs. ACE *Alera* POL 1 (y)	In-House (x) vs. ACE *Alera* POL 2 (y)	In-House (x) vs. ACE *Alera* POL 3 (y)
γ-GT	n	51	51	51
	Range	15 to 866	15 to 866	15 to 866
	Regression	y = 0.950x + 1.9	y = 1.028x + 2.9	y = 0.996x + 2.4
	Correlation	0.9998	0.9996	0.9997
	Std. Error Est.	3.7	5.4	4.6
	CI Slope	0.945 to 0.956	1.020 to 1.036	0.990 to 1.003
	CI Intercept	0.7 to 3.1	1.2 to 4.7	0.9 to 3.9
Lipase	n	51	50	51
	Range	15 to 676	15 to 676	15 to 676
	Regression	y = 1.028x + 3.3	y = 1.017x – 3.5	y = 0.992x – 2.9
	Correlation	0.9960	0.9969	0.9988
	Std. Error Est.	13.1	11.4	6.9
	CI Slope	1.001 to 1.054	0.993 to 1.040	0.978 to 1.006
	CI Intercept	-1.0 to 7.6	-7.3 to 0.3	-5.2 to -0.7
T4	n	50	50	48
	Range	1.5 to 18.6	1.5 to 18.6	1.5 to 18.6
	Regression	y = 1.022x – 0.14	y = 1.048x – 0.31	y = 1.033x – 0.10
	Correlation	0.9926	0.9909	0.9868
	Std. Error Est.	0.30	0.34	0.36
	CI Slope	0.986 to 1.058	1.007 to 1.089	0.983 to 1.083
	CI Intercept	-0.42 to 0.13	-0.63 to 0.01	-0.47 to 0.27

Performance Data:

ACE *Alera*

Performance data for the Alfa Wassermann ACE Reagents on the Alfa Wassermann ACE *Alera* Clinical Chemistry System

Detection Limits - ACE *Alera* Clinical Chemistry System

		γ-GT	Lipase	T4
LOB	**Original Data**	3 U/L	7 U/L	0.3 µg/dL
LOD	**Original Data**	5 U/L	11 U/L	0.8 µg/dL
LOQ	**2012 Data**	7 U/L	13 U/L	1.3 µg/dL

Linearity - ACE *Alera* Clinical Chemistry System

Reagent	Low Level Tested	High Level Tested	Linear to:	Linear Regression equation
γ-GT	4 U/L	993 U/L	950 U/L	y = 1.036x + 0.8
Lipase	11 U/L	739 U/L	700 U/L	y = 0.971x + 0.2
T4	1.2 µg/dL	19.7 µg/dL	19.6 µg/dL	y = 1.057x – 0.09

Performance Data:

ACE *Alera*

Interferences - ACE *Alera* Clinical Chemistry System

Interferent	No Significant Interference at or below:		
	γ-GT	Lipase	T4
Icterus	14.2 mg/dL	12.5 mg/dL	47.2 mg/dL
Hemolysis	125 mg/dL	1000 mg/dL	1000 mg/dL
Lipemia	500 mg/dL	803 mg/dL	1000 mg/dL
Ascorbic Acid	6 mg/dL	6 mg/dL	6 mg/dL

Heterophile Interferences – ACE T4 on the ACE *Alera* Clinical Chemistry System

Heterophile	No Clinically Interfering Condition at or below:
Human Anti-Mouse Antibody (HAMA)	800 ng/mL
Rheumatoid Factor	516 IU/mL

Cross-Reactivity – ACE T4 on the ACE *Alera* Clinical Chemistry System

Cross-Reactant	Concentration Tested (µg/dL)	% Cross-Reactivity
3,3',5,5'-Tetraiodothyroacetic Acid	5	18.4
L-Thyroxine	5	91.6
D-Thyroxine	5	68.0

Performance Data:

ACE *Alera*

Precision - ACE *Alera* Clinical Chemistry System

		Precision (SD, %CV)		
		Mean	**Within-Run**	**Total**
γ-GT U/L	Low	29	1.0, 3.4%	1.3, 4.7%
	Mid	71	1.4, 2.0%	2.4, 3.4%
	High	105	1.9, 1.8%	3.6, 3.4%
Lipase U/L	Low	63	6.2, 9.8%	6.2, 9.9%
	Mid	379	10.5, 2.8%	15.4, 4.1%
	High	657	20.4, 3.1%	24.4, 3.7%
T4 µg/dL	Low	6.0	0.19, 3.1%	0.34, 5.6%
	Mid	10.6	0.26, 2.4%	0.37, 3.5%
	High	17.1	0.56, 3.3%	0.66, 3.9%

Method Comparison - ACE *Alera* Clinical Chemistry System

In-House ACE (x) vs. In-House ACE *Alera* (y)

	γ-GT	**Lipase**	**T4**
n	51	49	50
Range	15 to 866 U/L	15 to 676 U/L	1.5 to 18.6 µg/dL
Slope	0.975	1.038	1.004
Intercept	4.3	-4.8	-0.08
Correlation Coefficient	0.9999	0.9995	0.9937
Std. Error	2.7	4.6	0.27
CI Slope	0.972 to 0.979	1.029 to 1.048	0.972 to 1.037
CI Intercept	3.5 to 5.2	-6.4 to -3.3	-0.33 to 0.17

Conclusions:	Based on the foregoing data, the device is safe and effective for use in clinical laboratories and physician office laboratories. These data indicate substantial equivalence for lithium heparin plasma sample collection tubes to the predicate device's use of serum sample collection tubes. These data also indicate that the ACE *Alera* Clinical Chemistry System is substantially equivalent to the predicate device ACE Clinical Chemistry System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 14, 2013

Alfa Wassermann Diagnostic Technologies, LLC
C/O Hyman Katz, Ph.D.
4 Henderson Drive
WEST CALDWELL NJ 07006

Re: K131515
Trade/Device Name: ACE T4 Reagent
ACE Lipase Reagent
ACE γ-GT Reagent
Regulation Number: 21 CFR 862.1700
Regulation Name: Total thyroxine test system
Regulatory Class: II
Product Code: KLI, CHI, JPZ
Dated: May 24, 2013
Received: May 28, 2013

Dear Dr. Katz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k131515

Device Name: ACE γ-GT Reagent

Indications for Use: The ACE γ-GT Reagent is intended for the quantitative determination of gamma-glutamyltransferase activity **in serum and lithium heparin plasma** using the ACE, ACE *Alera*, and ACE Axcel Clinical Chemistry Systems. Gamma-glutamyltransferase measurements are used in the diagnosis and treatment of liver diseases such as alcoholic cirrhosis and primary and secondary liver tumors. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only.

Device Name: ACE Lipase Reagent

Indications for Use: The ACE Lipase Reagent is intended for the quantitative determination of lipase activity **in serum and lithium heparin plasma** using the ACE, ACE *Alera*, and ACE Axcel Clinical Chemistry Systems. Lipase measurements are used in diagnosis and treatment of diseases of the pancreas such as acute pancreatitis and obstruction of the pancreatic duct. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices or Radiological Health (OIR)

Ruth A. Chesler -S

Division Sign-Off
Office of In Vitro Devices or Radiological Health
510(k) k131515

Indications for Use

510(k) Number (if known): k 131515

Device Name: ACE T4 Reagent

Indications for Use: The ACE T4 Reagent is intended for the quantitative determination of total thyroxine (T4) in **serum and lithium heparin plasma** using the ACE, ACE *Alera*, and ACE Axcel Clinical Chemistry Systems. Total thyroxine measurements are used in the diagnosis and treatment of thyroid diseases. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices or Radiological Health (OIR)

Ruth A. Chesler -S

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510(k) k131515